Zacks Equity Research

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Inhibitex, Inc. (INHX-NASDAQ)

INHX: Several Near-Term Catalyst Should Drive Inhibitex Shares Higher…

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	11/09/2010
Current Price (11/09/10)	$1.93
Target Price	**$4.00**

OUTLOOK

We believe that Inhibitex is poised for a big run over the next few months. The ongoing phase II program on FV-100 is expected to offer data in December 2010. FV-100 has the potential to be a game-changer for the treatment of herpes zoster, or shingles. Inhibitex is also progressing with a phase Ib program on nucleoside polymerase inhibitor, INX-189, with data expected early next year. INX-189 looks to have unrivaled potency in the genotype 1 replicon assay. INX-189 looks to be the most potent nucleotide polymerase inhibitor in clinical development. Both compounds present management with the opportunity to strike lucrative partnerships in 2011.

We are raising our rating on Inhibitex to 'Outperform' ahead of these major catalysts. Our price target is now $4.

SUMMARY DATA

52-Week High	**$2.95**
52-Week Low	**$0.75**
One-Year Return (%)	**96.04**
Beta	**1.17**
Average Daily Volume (sh)	**304,004**
Shares Outstanding (mil)	**62**
Market Capitalization ($mil)	**$123**
Short Interest Ratio (days)	**12.01**
Institutional Ownership (%)	**50**
Insider Ownership (%)	**25**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**24.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2010 Estimate	**N/A**
P/E using 2011 Estimate	**N/A**
Zacks Rank	**3**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**3 of 141**

ZACKS ESTIMATES

Revenue

(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	0.3 A	0.3 A	0.3 A	0.3 A	1.2 A
2010	1.0 A	0.3 A	0.3 A	0.8 E	2.4 E
2011					3.5 E
2012					5.0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	-$0.10 A	-$0.10 A	-$0.10 A	-$0.08 A	-$0.38 A
2010	-$0.08 A	-$0.09 A	-$0.08 A	-$0.09 E	-$0.34 E
2011					-$0.35 E
2012					-$0.27 E

Zacks Projected EPS Growth Rate - Next 4 Years % **N/A**

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WHAT'S NEW

Third Quarter Financial Review

On November 9, 2010, Inhibitex reported financial results for the third quarter ended September 30, 2010. Total revenues in the quarter were $0.3 million and were comprised of $0.250 million in collaborative R&D payments from Pfizer on licensing the company's MSCRAMM technology, as well as a $0.0375 million licensing and milestone payments. Revenues were right in-line with our expectations. Net loss for the first quarter totaled $5.3 million, or $0.08 per share. This also was in-line with our financial forecast.

The company exited the third quarter ended September 30, 2010 with $24.2 million in cash and investments. We believe the current cash balance is sufficient to fund operations into the second half of 2011.

FV-100 Update

It's been smooth sailing so far for the company's phase II program on FV-100. Since initiated in May 2009, the independent data safety monitoring board (DSMB) responsible for reviewing safety data from the trial has met three times to review 30-day follow-up safety data from the first, second and third quartiles. After each time, most recently as of July 22, 2010, the DSMB recommended the trial continue on plan. Finally, in October 2010, the trial completed enrollment at ~350 patients. Management expects to report top-line data in December 2010.

As a reminder, the phase II program is a well-controlled, double-blind, clinical trial evaluating FV-100 against an active control of Glaxo's Valtrex (valacyclovir). Roughly 350 patients, aged 50 years and older, were randomized to one of three treatment arms: 200 mg FV-100 administered once daily; 400 mg FV-100 administered once daily; and 1,000 mg valacyclovir administered three times per day. The primary endpoint of the trial is a reduction in herpes zoster associated pain and severity as measured by the Zoster burden of illness (ZBOI) scale after 30 days of treatment. The Z-BOI is a composite endpoint that encompasses both pain and dermatological endpoints.

The trial is 80% powered to detect an approximate 25% difference between the FV-100 and Valtrex cohorts. Management's initial market research shows that a minimum of a 10% to 15% improvement in pain reduction vs. valacyclovir would be enough to garner meaningful physician interest without payor pushback. In addition to the primary endpoint, Inhibitex will also report: 1) reduction in ZBOI after 14 days, 2) reduction in ZBOI after 90 days, 3) incidence of post herpetic neuralgia (PHN), 4) mean time to lesion crusting or healing, and 5) use of concomitant pain medications.

The next step for management following completion of the phase II trial would be to schedule an End-of-Phase II meeting with the U.S. FDA around the middle of 2011. We expect that Inhibitex will look to push FV-100 into a pivotal phase III program shortly thereafter. Our best guess is that the phase III program will include two concurrent programs, with a total enrollment of around 1000 patients, and take an estimated two years to complete. Inhibitex plans a global program, so a meeting with the EMEA will need to take place in 2011 as well.

If all goes well, we could be looking at a new drug application (NDA) on FV-100 around 2014, with U.S. FDA action in 2015. We note that management has mentioned being in discussion with potential partners on FV-100, and we fully expect a deal in 2011. However, at this point it remains to be seen whether or not a deal is signed prior to the initiation of a phase III program. We note the longer management waits to partner FV-100, potentially the better economics management can negotiate for shareholders.

INX-189 Update

During the first quarter 2010, management initiated a phase Ia trial on INX-189, the company's high potency nucleoside NS5b polymerase inhibitor for the treatment of hepatitis C (HCV). The phase Ia trial wa a double-blind, placebo-controlled, single ascending dose study to evaluate the safety and pharmacokinetics of INX-189 in healthy volunteers all in the U.S. (single site). The trial employed six escalating doses of INX-189, ranging from 3 mg up to 100 mg, or placebo. The program completed in September 2010. Full data and a detailed analysis will be available at a scientific meeting during the spring 2011. However, top-line results demonstrated:

- ✓ INX-189 was generally well tolerated at all dose levels
- ✓ No drug-related serious adverse events
- ✓ No dose-related trends in frequency of type of even, with the most common adverse events being headache and nasal congestion.
- ✓ No grade II or higher laboratory abnormality adverse events or clinically significant changes in ECG
- ✓ Pharmacokinetic (pk) data that supports potential once-daily dosing, with excellent conversion of INX-189 to the active metabolite and minimal residual INX-189 in plasma.

In November 2010, Inhibitex initiated a phase Ib multiple ascending dose (MAD) clinical trial to assess the ability of once-daily INX-189 to reduce HCV RNA viral loads in treatment naïve patients with chronic genotype-1 HCV, as well as safety, tolerability, and pharmacokinetics, after seven days of treatment.

Each treatment cohort will include 10 patients, eight of which will receive INX-189 and two of which will receive placebo. Dose ranges will include 9mg, 25mg, and 50mg for seven days, and 50mg for the first day (load dose) followed by 9mg for six days, or placebo. In addition to evaluating INX-189 as monotherapy, Inhibitex plans to evaluate two dose levels of INX-189 administered once daily for seven days in combination with ribavirin, the standard of care for the treatment of HCV. Preclinical data suggests significant synergy between INX-189 and ribavirin. The dose levels of INX-189 to be evaluated in combination with ribavirin will be determined based upon the results of the monotherapy cohorts. Data from this program should be available in early 2011.

Management should be in position to advance INX-189 in a phase II, 12+ week clinical trial in combination with standard of care and other complementary direct antiviral compounds by the middle of 2011. We expect that management will partner the candidate for the phase II program in 2011 assuming safety and proof-of-concept have been effectively demonstrated.

Well Positioned With Catalysts Ahead

Inhibitex exited the third quarter 2010 with $24.2 million in cash and investments. This should be enough to fund operations, including presenting the full data from the phase II FV-100 program and completing a phase Ib monotherapy and ribavirin combination program on INX-189 in early 2011. We estimate that the company will still have roughly $18 million in cash on hand at the end of the year.

Inhibitex may be in need of cash at some point in 2011. However, with the potential to partner both FV-100 and INX-189, as well as receive additional milestone from Pfizer on SA3Ag, we believe there is significant opportunity to raise non-dilutive cash in 2011.

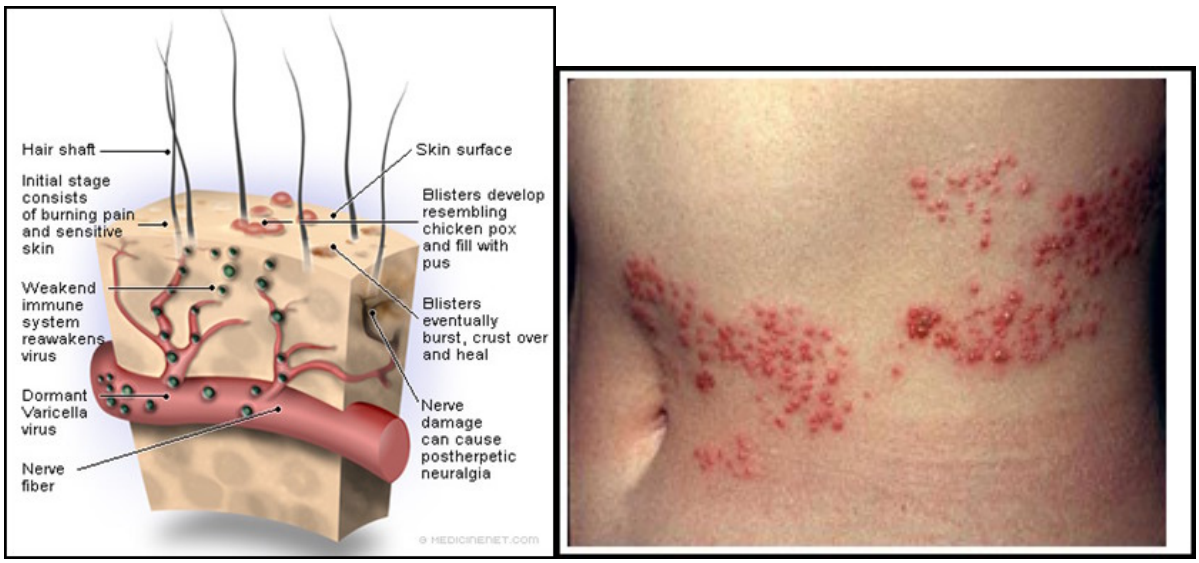
There is significant interest from partners on both molecules. We think with key data expected on both over the next 2 – 3 months, Inhibitex shares are poised for a meaningful run. A market capitalization of $120 million under-values the potential for the company. Both FV-100 and INX-189 offer $500+ million opportunities. We think that 2011 has the potential to be a big year for Inhibitex with signing major development collaborations on both drugs. Accordingly, we recommend investors start acquiring the shares now ahead of these major catalysts coming in the next few months. Our target is $4 per share.

OVERVIEW

FV-100

The leading product candidate at Inhibitex is FV-100, an orally available bicyclic nucleoside analogue prodrug being developed for the treatment of shingles (herpes zoster), which is caused by varicella zoster virus (VZV).

- Varicella Zoster, a DNA virus and member of the herpes family, is the virus that causes chickenpox during childhood. After the chickenpox infection subsides, VZV remains latent in the dorsal root and cranial nerve ganglia. Individuals who have had chickenpox are at risk for reactivation of the VZV virus, known as shingles. Although shingles can occur in any individual with a prior VZV infection, its incidence varies with age and immune status, which are the key risk factors. In 2008, there were an estimated 1.2 million new cases of shingles in the U.S. In Europe and Japan, the estimated number of shingles cases is 1.0 and 0.4 million, respectively. Shingles is largely a disease of the aged, with over 50% of all cases occurring in individuals over the age of 60, and approximately 80% of the cases occurring in individuals over the age of 40. Incidence is often un-reported because the CDC does not require notification for a herpes zoster flare-up. Inhibitex estimates that approximately 20-30% of all persons in the U.S. will suffer from shingles during their lifetime. The pain associated with an episode of shingles is a result of damage to the nerve fibers caused by the replication of VZV and the subsequent inflammation associated with the infection. Pain symptoms are commonly described as a burning sensation, with bouts of stabbing and shooting pain.



Published preclinical data demonstrates that FV-100 is significantly more potent against VZV than older generation nucleoside analogue drugs commonly used to treat herpes such as acyclovir, valacyclovir, famciclovir. Patients often take multiple medications during flare-up, leaving the door open to a potential more potent single agent. Preclinical studies further demonstrate that FV-100 has a more rapid onset of antiviral activity and can fully inhibit the replication of VZV more rapidly than currently used drugs at significantly lower concentration levels. Inhibitex estimates that FV-100 is 10,000 the potency of acyclovir *in vitro*, with onset of action in as little as two hours post-dosing. Valtrex (valacyclovir), the current market leader sold by GlaxoSmithKline, posted worldwide sales of $2.2 billion in 2008, up 16% from 2007 levels. U.S. sales of Valtrex totaled $1.6 billion, up 20%. However, the majority of Valtrex use is for non-shingles indications such as herpes simplex 1 and 2. Still, there were an estimated 2.5 million prescriptions written for herpes zoster in 2008, and Valtrex has an estimated 55% market share even in the face of cheaper generic competition from acyclovir and famciclovir thanks to improved bioavailability and less frequent dosing. Inhibitex is currently conducting human clinical trials with FV-100 testing its hypothesis that the drug can reduce the incidence, severity, and duration of shingles-related symptoms, including lesions, acute pain, and post herpetic neuralgia (PHN) relative to Valtrex.

- PHN is a persistent neuropathic pain condition caused by nerve damage after a shingles, or herpes zoster, viral infection and afflicts approximately one in five patients diagnosed with shingles (~200k individuals) in the U.S. The incidence of PHN increases in elderly patients, with 75% of those over 70 years old who have shingles, developing PHN. The pain associated with PHN reportedly can be so severe that patients are unable to resume normal activities for months. There are a number of treatment options for PHN including antidepressants, anticonvulsants (such as gabapentin or pregabalin) and topical agents such as lidocaine patches or capsaicin lotion. Opioid analgesics may also be appropriate in the most severe situations.

…Phase II Data In December 2010…

In May 2009, Inhibitex initiated a well-controlled, double-blind, phase II clinical trial evaluating FV-100 against an active control of Glaxo's Valtrex (valacyclovir). Approximately 350 patients, aged 50 years and older, will be equally randomized to one of three treatment arms: 200 mg FV-100 administered once daily; 400 mg FV-100 administered once daily; and 1,000 mg valacyclovir administered three times per day.

The primary endpoint is a reduction in herpes zoster associated pain and severity as measured by the Zoster Burden of Illness (ZBOI) scale after 30 days. The trial is 80% powered to detect an approximate 25% difference between the area under the curve (AUC) of the FV-100 and valacyclovir cohorts.

	Reduction in ZBOI (AUC) (Day – 30)
200mg FV-100 QD (n~115)	*…TBD*
400mg FV-100 QD (n~115)	*…TBD*
1000 mg Valtrex TID (n~115)	*…TBD*

The trial is 80% powered to detect an approximate 25% difference between the FV-100 and Valtrex cohorts. The primary endpoint is an interesting one because Inhibitex is directly comparing their drug to Glaxo's $2.2 billion blockbuster Valtrex. However, as noted above, the majority of Valtrex use is not for a shingles indication. Based on IMS Health data, we estimate that only roughly 20% of Valtrex's $1.6 billion U.S. sales are for shingles. Valtrex is not approved for the reduction of acute pain and PHN, and the three-times daily dosing is a significant impediment to compliance. Management's initial market research shows that a minimum of a 10% to 15% improvement in pain reduction vs. valacyclovir would be enough to garner meaningful physician interest without payor pushback.

In addition to the primary endpoint, Inhibitex will also report: 1) reduction in ZBOI after 14 days, 2) reduction in ZBOI after 90 days, 3) incidence of post herpetic neuralgia (PHN), 4) mean time to lesion crusting or healing, and 5) use of concomitant pain medications.

…Phase III To Start Mid-2011…

The next step for management following completion of the phase II trial would be to schedule an End-of-Phase II meeting with the U.S. FDA around the middle of 2011. We expect that Inhibitex will look to push FV-100 into a pivotal phase III program shortly thereafter. Our best guess is that the phase III program will include two concurrent programs, with a total enrollment of around 1000 patients, and take an estimated two years to complete. Inhibitex plans a global program, so a meeting with the EMEA will need to take place in 2011 as well.

If all goes well, we could be looking at a new drug application (NDA) on FV-100 around 2014, with U.S. FDA action in 2015. We note that management has mentioned being in discussion with potential partners on FV-100, and we fully expect a deal in 2011. With positive phase II data versus Valtrex, Inhibitex should be in a very strong position to partner the drug with a larger pharmaceutical company for pivotal phase III testing.

…Commercialization Plans…

FV-100 has several differentiating characteristics that could catapult it into the market leading position for herpes zoster shortly after approval. Among these include a favorable tolerability and safety profile, strong pharmacokinetic rapid absorption with potent anti-viral activity profile, convenient once-daily dosing – a very strong potential driver of scripts in the elderly – and the potential that FV-100 can be freely used in patients with insufficient renal function, unlike Valtrex. Therefore, even if the phase II data above only proves that FV-100 is on-par in terms of efficacy to Valtrex, Inhibitex has a significant market opportunity by offering once-daily dosing and improved safety performance in patients with renal insufficiency.

Branded Valtrex sells for roughly $275 per script (undiscounted). Generic valacyclovir, acyclovir and famciclovir sell for about half that price at around $150 – 200 per script. Depending on the success of the phase II program, we suspect that FV-100 will be priced competitively with branded Valtrex. However, even with a price comparable to Valtrex, we believe there is significant pharmaco-economics that could benefit FV-100 even in the face of cheaper generic alternatives. Once daily dosing is a major advantage over 3x/daily Valtrex and 5x/daily acyclovir, and could reduce the number of necessary re-treats due to non-compliance. With on par efficacy alone, FV-100 could capture nearly 40% of the market. After all, branded Valtrex maintained >50% market share even in the face of generic famciclovir and acyclovir, due mainly to its dosing advantage, throughout 2008 and 2009. Valtrex lost exclusivity in November 2009, and the entire market has now become genericized, with valacyclovir holding significant share.

With homerun phase II data – meaning a significant reduction in ZBOI vs. Valtrex – market share could eclipse 65%, meaning potential peaks sales in the U.S. are $400 million. Outside the U.S., the drug may be able to capture another $300 million, making worldwide peak sales in the $700 million range. Impediments to gaining market share are cost vs. the three generics and the potential re-formulation of Valtrex by a drug delivery company that could improve the dosing from three-time daily to twice-daily or even once-daily. As of yet, we are unaware of any generic / drug delivery company working on an extended release Valtrex product.

	valacyclovir	**famciclovir**	**acyclovir**	**FV-100**
Dose:	1000mg 3x/day	500mg 3x/day	800mg 5x/day	400mg 1x/day
Lesion Healing:	++	+	+	+++
Reduction in Pain / PHN:	++	+	+	+++
Adjust for Renal Insufficiency:	Required	Required	Required	Not-required

Hepatitis C Protides / INX-189

Inhibitex is currently working on a series of nucleoside polymerase inhibitors for the treatment of chronic hepatitis C caused by the hepatitis C virus (HCV). More specifically, the company is developing a series of phosphoramidate nucleoside analogues, also referred to as pronucleotides or protides, which are prodrugs of nucleosides that target the RNA-dependent RNA polymerase ("NS5b") of HCV.

- HCV is a leading cause of chronic liver disease, including cirrhosis, organ failure and cancer, and the leading cause of death from liver disease in the U.S. HCV is often found among hemodialysis patients, hemophiliacs and recipients of blood transfusions before 1992. HCV is now transmitted primarily through injection drug use and by pregnant women infecting their children *in utero*. WHO estimates that nearly 180 million people worldwide, or approximately 3% of the world's population, are infected with HCV. Of these individuals, 130 million are chronic HCV carriers with an increased risk of developing liver cirrhosis or liver cancer.

  HCV is responsible for more than half of all liver cancer cases and two-thirds of all liver transplants in the developed world. It is estimated that 3 to 4 million people worldwide are newly infected each year, the majority of whom will develop chronic hepatitis C. The U.S. CDC estimates that approximately 3.2 million people in the U.S. are chronically infected with HCV. Because symptoms of this chronic disease do not typically appear until its later stages, carriers often do not realize they are infected, and therefore serve as a source of transmission.

Management believes that the protide approach possesses several pharmacological advantages over earlier, first generation approaches that use the parent nucleoside (non-phosphorylated) alone. These include a significant increase in antiviral activity, higher concentrations of the anti-virally active triphosphate in liver, and potentially less toxicity due to reduced systemic exposure.

The FDA has not yet approved any NS5b polymerase inhibitors for the treatment of HCV infection, but several pharmaceutical and biotechnology companies, including Pharmasset and Idenix, are developing similar product candidates that target the HCV polymerase. Both companies recently offered-up very encouraging phase I data in July / August 2009. This has created a spark of enthusiasm from larger organization on potential partnering / co-development opportunities, and we expect that Inhibitex will be at the center of these discussions over the next few years. The most advanced nucleoside polymerase inhibitors are currently in phase II clinical trials.

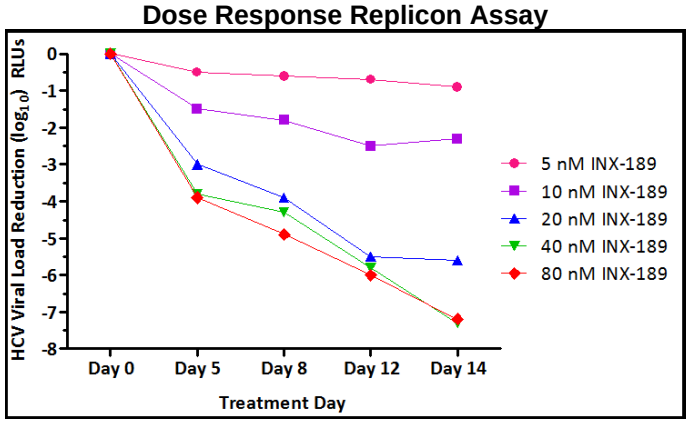
…Impressive Preclinical Profile…

Preclinical data suggests INX-189 has unrivaled potency in genotype 1 replicon assay. We believe INX-189 is the most potent nucleotide polymerase inhibitor in clinical development, with pharmacokinetic data suggesting once-a-day therapy. Preclinical profile of INX-189 suggests: rapid onset of anti-viral activity, a long half-life that could allow for once daily dosing, low toxicity, and a potential synergistic mechanism with ribavirin. This is certainly something to be excited about.

Concentration (μm)	EC-50 (geno 1b)	Replicon Clearance 14-Days
INX-189 (Inhibitex)	0.014	0.02
PSI-7851 (Pharmasset)	0.090	N/D
IDX-184 (Idenix)	0.430	2.5
VCH-222 (Vertex)	0.012	N/D
PF-00868554 (Pfizer)	0.075	N/D
HCV-796 (ViroPharma)	0.045	Failed

In November 2010, Inhibitex presented three poster presentations at the American Association for the Study of Liver Disease (AASLD) characterizing INX-189. The first poster, Characterization of in vitro selected Hepatitis C Virus Replicon Mutants Resistant to the Phosphoramidate Analog of 2'-C-Methylguanosine, INX-189, offers data suggesting a low likelihood for viral mutations escaping inhibition by INX-189. The second and third poster, Metabolite Characterization of INX-189, a Potent HCV Inhibitor, in Fresh Human Primary Hepatocytes and Human Liver and Kidney Cell Lines and In Vitro and In Vivo Metabolism of INX-189, a Potent HCV Inhibitor, in Rat and Cynomolgus Monkey Hepatocytes, both characterize the key metabolites of INX-189 metabolism and suggests analytical methods to identify and quantify them.

Dose Response Replicon Assay



…Phase I Ongoing…

During the first quarter 2010, management initiated a phase Ia trial on INX-189, the company's high potency nucleoside NS5b polymerase inhibitor for the treatment of hepatitis C (HCV). The phase Ia trial wa a double-blind, placebo-controlled, single ascending dose study to evaluate the safety and pharmacokinetics of INX-189 in healthy volunteers all in the U.S. (single site). The trial employed six escalating doses of INX-189, ranging from 3 mg up to 100 mg, or placebo. The program completed in September 2010. Full data and a detailed analysis will be available at a scientific meeting during the spring 2011. However, top-line results demonstrated:

- ✓ INX-189 was generally well tolerated at all dose levels
- ✓ No drug-related serious adverse events
- ✓ No dose-related trends in frequency of type of even, with the most common adverse events being headache and nasal congestion.
- ✓ No grade II or higher laboratory abnormality adverse events or clinically significant changes in ECG
- ✓ Pharmacokinetic (pk) data that supports potential once-daily dosing, with excellent conversion of INX-189 to the active metabolite and minimal residual INX-189 in plasma.

In November 2010, Inhibitex initiated a phase Ib multiple ascending dose (MAD) clinical trial to assess the ability of once-daily INX-189 to reduce HCV RNA viral loads in treatment naïve patients with chronic genotype-1 HCV, as well as safety, tolerability, and pharmacokinetics, after seven days of treatment.

Each treatment cohort will include 10 patients, eight of which will receive INX-189 and two of which will receive placebo. Dose ranges will include 9mg, 25mg, and 50mg for seven days, and 50mg for the first day (load dose) followed by 9mg for six days, or placebo. In addition to evaluating INX-189 as monotherapy, Inhibitex plans to evaluate two dose levels of INX-189 administered once daily for seven days in combination with ribavirin, the standard of care for the treatment of HCV. Preclinical data suggests significant synergy between INX-189 and ribavirin. The dose levels of INX-189 to be evaluated in combination with ribavirin will be determined based upon the results of the monotherapy cohorts. Data from this program should be available in early 2011.

Management should be in position to advance INX-189 in a phase II, 12+ week clinical trial in combination with standard of care and other complementary direct antiviral compounds by the middle of 2011. We expect that management will partner the candidate for the phase II program in 2011 assuming safety and proof-of-concept have been effectively demonstrated. With phase I concept data that confirms the exciting preclinical work and management's optimism on the drug, INX-189 could fetch $100 million or more in a development partnership. We remind investors that in March 2009, Vertex Pharmaceuticals paid nearly $400 million to acquire privately-held ViroChem and its HCV non-nucleoside N25b polymerase inhibitor, VCH-222. Inhibitex' nucleosides N25b polymerase inhibitor looks to offer similar potency (EC-50 of 14 nm for INX-189 vs. 12nm for VCH-222) with potentially less resistance and improved dosing.

Pfizer Starts Phase I on SA3Ag

In early January 2010, Pfizer reported to Inhibitex that it had initiated patient recruitment for 408-patient, randomized, double-blind phase I clinical trial to evaluate the safety, tolerability, and immunogenicity of three ascending dose levels of a 3-antigen *Staphylococcus aureus* vaccine (SA3Ag) in healthy adults. The SA3Ag vaccine contains an antigen originating from Inhibitex' MSCRAMM protein platform. Management licensed its MSCRAMM protein platform to Wyeth (acquired by Pfizer in 2009) on an exclusive worldwide basis for the development of active vaccines against staphylococcus in 2001. Pfizer is responsible for all clinical development, manufacturing and marketing of the vaccine. Inhibitex earned a $0.7 million milestone payment upon the initiation of the phase I program, and is eligible to receive milestones, as well as royalties on future net sales. This $0.7 million milestone was recognized fully in the first quarter 2010.

RECOMMENDATION

FV-100 a Game Changer…

Inhibitex lead development candidate, FV-100, has the potential to be a game changer for the treatment of herpes zoster, or shingles. The current standard of care, Glaxo's Valtrex (valacyclovir), with an estimated 55% market share, is dosed at 1000mg three times a day. Valtrex has improved lesion healing and pain indication reduction over older drugs Famvir (famciclovir) and Zovirax (acyclovir), but the treatment option can still be improved upon significantly. Inhibitex is developing FV-100, a potential once daily dosing agent, currently in a phase II trial. The trial is designed to show FV-100 is superior to Valtrex on pain and severity reduction after 30 days, the primary endpoint, as well as show superiority on key secondary endpoints including: pain after 90 days, incidence of post herpetic neuralgia (PHN), mean time to lesion healing, and use of concomitant pain medications.

If successful, we believe that Inhibitex' drug has $500+ million peak sales worldwide. However, even with efficacy only on par with Valtrex, we still believe that FV-100 has commercial potential given the reduction in dosing (improved compliance – especially in the elderly population) from three times daily to once daily.

FV-100 Peak Sales (in Millions)		
Scenario:	Base	…phase II efficacy on par with Valtrex, primary driving force is QD dosing vs. TID for Valtrex
FV-100 Price:	$225	per Rx
FV-100 Market Share:	40%	…takes sizable share from Valtrex, but generics still hold onto 40% of the market
Market Opportunity (U.S.):	$203	…peak U.S. sales
Market Opportunity (Ex-U.S.):	$142	…about 70% of U.S. sales
Total Peak Sales	$345	…under "Base" case scenario
Scenario:	Bull	…phase II efficacy superior to Valtrex, primary driving force is both efficacy and dosing
FV-100 Price:	$275	per Rx
FV-100 Market Share:	65%	…takes sizable share from both Valtrex and all generics
Market Opportunity (U.S.):	$403	…peak U.S. sales
Market Opportunity (Ex-U.S.):	$302	…about 75% of U.S. sales
Total Peak Sales	$705	…under "Bull" case scenario

INX-189 Could Be Huge…

Inhibitex' HCV phosphoramidate nucleoside analogue (protide) candidate, INX-189, could be a potential blockbuster given its rapid onset, favorable once daily dosing, high potency activity, and improved tolerability profile. Preclinical *in vitro* data has been very impressive. Plus, INX-189 could have potential synergistic benefits with ribavirin, making the drug an excellent add-on therapy to standard of care. With phase I concept data that confirms the exciting preclinical work and management's optimism on the drug, INX-189 could fetch $100 million or more in a development partnership. We remind investors that in March 2009, Vertex Pharmaceuticals paid nearly $400 million to acquire privately-held ViroChem and its HCV non-nucleoside N25b polymerase inhibitor, VCH-222. Inhibitex' nucleosides N25b polymerase inhibitor looks to offer similar potency with potentially less resistance and improved dosing. Phase Ib concept data is expected early 2011. Two other phosphoramidate candidates, Pharmasset's PSI-7851 and Idenix' IDX-184, are over a year ahead of INX-189 in development, although we note neither candidate looks as potent as INX-189.

PROJECTED FINANCIALS

Inhibitex, Inc.
Income Statement

	2008 A	2009 A	Q1 A	Q2 A	Q3 A	Q4 E	2010 E	2011 E	2012 E	2013 E
FV-100 (U.S.)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
FV-100 (Ex-U.S.)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
FV-100 Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
INX-189	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Collaborative R&D	$1.5	$1.0	$0.3	$0.3	$0.3	$0.3	$1.0	$2.5	$2.5	$2.5
License Fees & Milestones, Grants	$1.7	$0.2	$0.7	$0.0	$0.0	$0.5	$1.4	$1.0	$2.5	$5.0
Total Other Revenues	**$3.2**	**$1.2**	**$1.0**	**$0.3**	**$0.3**	**$0.8**	**$2.4**	**$3.5**	**$5.0**	**$7.5**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$3.2**	**$1.2**	**$1.0**	**$0.3**	**$0.3**	**$0.8**	**$2.4**	**$3.5**	**$5.0**	**$7.5**
YOY Growth	-	*-63.5%*	-	-	-	-	*104.4%*	*48.9%*	*42.9%*	*50.0%*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$0.0	$0.0	$0.0
Product Gross Margin	*100.0%*	-	-	-	-	-	-	-	-	-
SG&A	$5.1	$3.6	$1.0	$1.0	$0.9	$1.0	$3.9	$4.5	$4.7	$5.0
% SG&A	-	-	-	-	-	-	*164.2%*	*128.6%*	*94.0%*	*66.7%*
R&D	$12.7	$15.4	$4.8	$4.9	$4.7	$5.5	$19.9	$21.5	$18.0	$18.0
% R&D	-	-	-	-	-	-	*846.8%*	*614.3%*	*360.0%*	*240.0%*
Operating Income	($14.5)	($17.8)	($4.8)	($5.6)	($5.3)	($5.7)	($21.4)	($22.5)	($17.7)	($15.5)
Interest & Other Net	$1.3	$0.2	$0.0	$0.0	$0.0	$0.0	$0.1	$0.2	$0.2	$0.2
Pre-Tax Income	($13.2)	($17.6)	($4.8)	($5.6)	($5.3)	($5.7)	($21.3)	($22.3)	($17.5)	($15.3)
Taxes / Other	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($13.2)	($17.6)	($4.8)	($5.6)	($5.3)	($5.7)	($21.3)	($22.3)	($17.5)	($15.3)
YOY Growth	-	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.31)**	**($0.38)**	**($0.08)**	**($0.09)**	**($0.08)**	**($0.09)**	**($0.34)**	**($0.35)**	**($0.27)**	**($0.23)**
YOY Growth	-	-	-	-	-	-	*-8.8%*	*1.4%*	*-23.9%*	*-15.1%*
Shares Outstanding	43.1	46.7	61.6	61.8	62.2	62.4	62.0	64.0	66.0	68.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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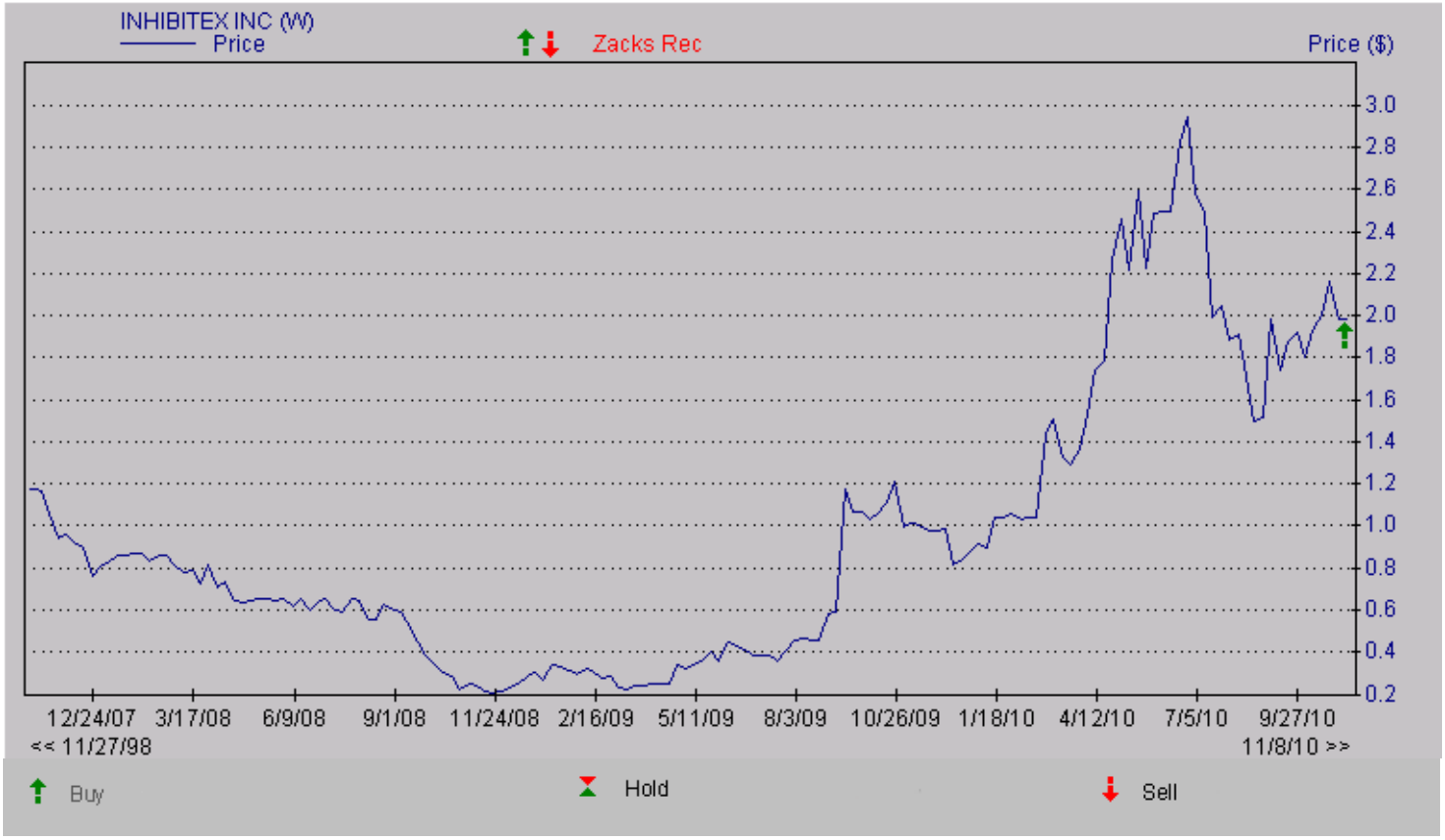

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